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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,754	10/15/2001	Joseph A. Orr	5072US	2866

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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

7

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,754

Applicant(s)

ORR ET AL.

Examiner

Patricia C. Mallari

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Response to Arguments

The preliminary amendment filed by the applicants on January 14, 2002 (paper no. 4) has been received and entered. The Office Action filed September 30, 2003 (paper no. 5) responded to the claims as written in the preliminary amendment.

The applicants' arguments with respect to claims 1-11, 14, 15, 19, 20, and 24 have been considered but are moot in view of the new ground(s) of rejection.

The indicated allowability of claims 12, 13, 16-18, and 21-23 is withdrawn in view of the newly discovered reference(s) to US Patent No. 5,823,184 to Gross and US Patent No. 5,769,702 to Hanson. Rejections based on the newly cited references follow.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a breathing apparatus" on line 3 of the claim and "a conduit including a first end coupled to a mouthpiece" on line 4 of the claim. Claim 2 recites, "wherein the breathing apparatus comprises a mouthpiece", and the specification discloses the breathing apparatus as being the same as the mouthpiece (see p.6, paragraph 24). It is unclear whether the mouthpiece and the breathing apparatus in claim 1 are the same or if they constitute separate elements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,823,184 to Gross. Gross discloses a breathing conduit 24, 26 comprising a first end configured to be coupled to a breathing apparatus 28, a second end 16 configured to be coupled to an apparatus 10 for monitoring the individual's respiration, and at least a section 24, 26 located between the first end and the second end 16 configured to be formed to a desired shape and substantially maintain that shape until formed to another desired shape. The breathing conduit 24, 26 is longitudinally collapsible and expandable and comprises corrugated tubing (figs. 1, 4, 8; col. 5, lines 3-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 12, 13, 15-17, 19-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,581,595 to Murdock et al. in view of US Patent No. 5,823,184 to Gross. Murdock discloses a breath collection system

comprising a breathing apparatus 26 configured to communicate with at least a mouth of the individual and a conduit 24 including a first end coupled to a mouthpiece 26 or mask 30 and a second end configured to be coupled to an apparatus 12 for monitoring the individual's respiration (figs. 1-3). Use of the apparatus occurs prior to sleep, at nighttime, or upon waking, indicating the patient would be in a resting position (col. 7, lines 45-65). The connection between the mouth of the patient and the mouthpiece 26 is substantially fluid tight to the degree that the device functions correctly in providing sufficient air to the patient and in accurate indirect calorimetry measurements. The conduit 24 is shown as being flexible and accordion-like in figure 3 (col. 3, lines 39-50), but the reference is silent as to other qualities of the conduit 24.

However, Gross discloses breathing circuit 10 having a flexible tube 24, 26 comprising accordion-like or corrugated, expandable, contractible, and positionable tubing capable of assuming any bent configuration selected by a user and retaining that configuration until positioned into another bent or straight configuration (col. 5, lines 3-17; figs. 1, 4, and 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the flexible tube of Gross as the conduit in the apparatus of Murdock et al., because Murdock discloses using a flexible tube as the conduit and Gross describes such a flexible tube. Regarding the method claims 19-21 and 23, the description of the apparatus inherently discloses the method of its use.

Claims 1-3, 6-13, 15-17, 19-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,042,501 to Kenny et al. in view of Gross. Kenny teaches a breath collection system usable for obtaining metabolic measurements

(col. 7, lines 35-50), comprising a breathing apparatus 110 configured to communicate with at least a user's mouth and a flexible conduit 120 including a first end coupled to a mouthpiece 110 and a second end configured to be coupled to a monitoring apparatus 120. The mouthpiece 110 has one-way inlet valve 111 and outlet valve 112. The outlets facilitate the introduction of inhalation gases 113, indicating that inlet valve 111 opens upon application of negative pressure, and the evacuation of expiratory gases 115 from breathing apparatus 110, similarly indicating that outlet valve 112 opens upon application of positive pressure. A tracheotomy tube or other apparatus may be used in place of the mouthpiece (fig. 1). The apparatus may be used during rest (col. 7, lines 51-55). The connection between the patient's mouth and the mouthpiece 110 is substantially fluid tight to the degree that the apparatus functions correctly in obtaining breath samples from the patient. Kenny is silent as to the features of the flexible conduit.

However, Gross discloses breathing circuit 10 having a flexible tube 24, 26 comprising accordion-like or corrugated, expandable, contractible, and positionable tubing capable of assuming any bent configuration selected by a user and retaining that configuration until positioned into another bent or straight configuration (col. 5, lines 3-17; figs. 1, 4, and 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the flexible tube of Gross as the conduit in the apparatus of Kenny, since Kenny discloses using a flexible conduit, and Gross describes a suitable flexible conduit to use. Regarding method claims 19-21 and 23, the description of the apparatus inherently discloses the method of its use.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny in view of Gross, as applied to claims 1-3, 6-13, 15-17, 19-21, and 23 above. Kenny, as modified, fails to show the conduit coupling section of the mouthpiece 110 oriented in a downwardly extending direction relative to the breathing end. However, the applicants have not disclosed that having the coupling section oriented in such a direction solves any stated problem or is for any particular purpose. Moreover, it appears that the breath collection system would perform equally well with the coupling section in the orientation shown in Figure 1 of Kenny. Accordingly, the use of the downward orientation of the conduit coupling section is deemed to be a design consideration which fails to patentably distinguish over the prior art of Kenny, as modified by Gross.

Claims 14, 18, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murdock et al. in view of Gross, as applied to claims 1, 2, 5, 12, 13, 15-17, 19-21, and 23, and further in view of US Patent No. 5,769,702 to Hanson. Murdock, as modified fails to teach at least a section of the conduit carrying at least one elongate member. However, Hanson teaches a fluid conduit 10 for providing or removing gases comprising a malleable positioning tube 20. The tube 20 may comprise either accordion-like tubular bellows, allowing one to extend, contract, and position the tube, or it may comprise at least one malleable wire (elongate compliant member) affixed to the positioning tube, where the wire may be bent to maintain the tube 20 in a desired shape (col. 3, lines 32-60, figs. 5-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the malleable wire in place of the accordion tube Murdock et al. in view of Gross, since Hanson discloses the

functional equivalence between an accordion-like tube and a tube having a malleable wire affixed to it.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenny in view of Gross, as applied to claims 1-3, 6-13, 15-17, 19-21, and 23 above, and further in view of US Patent No. 5,308,792 to Mault. Kenny, as modified by Gross, fails to teach restricting respiration through the nose of a patient. However, Mault discloses an indirect calorimeter wherein a user 10 exhales into a mouthpiece 12. A nose clamp 14 may be employed in connection with the mouthpiece 12 (fig. 1, col. 3, line 65-col. 4, line 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Mault with that of Kenny, as modified by Gross, in order to ensure that all respiratory air passes through the mouthpiece, thereby ensuring a more accurate measurement.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,461,200 to Norcia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AU 3736